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**Stand Out in Class: Restructuring the classroom environment to reduce sitting time**  
**– findings from a pilot cluster randomised controlled trial**

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## 27 **Abstract**

28 **Background:** Excessive sedentary behaviour (sitting) is a risk factor for poor health in  
29 children and adults. Incorporating sit-stand desks in the classroom environment has been  
30 highlighted as a potential strategy to reduce children's sitting time. The primary aim of this  
31 study was to examine the feasibility of conducting a cluster randomised controlled trial  
32 (RCT) of a sit-stand desk intervention within primary school classrooms.

33 **Methods:** We conducted a two-armed pilot cluster RCT involving 8 primary schools in  
34 Bradford, United Kingdom. Schools were randomised on a 1:1 basis to the intervention or  
35 usual practice control arm. All children (aged 9-10 years) in participating classes were  
36 eligible to take part. Six sit-stand desks replaced three standard desks (sitting 6 children)  
37 in the intervention classrooms for 4.5-months. Teachers were encouraged to use a rotation  
38 system to ensure all pupils were exposed to the sit-stand desks for >1 hour/day on  
39 average. Trial feasibility outcomes (assessed using quantitative and qualitative measures)  
40 included school and participant recruitment and attrition, intervention and outcome  
41 measure completion rates, acceptability, and preliminary effectiveness of the intervention  
42 for reducing sitting time. A weighted linear regression model compared changes in  
43 weekday sitting time (assessed using the activPAL accelerometer) between trial arms.

44 **Results:** School and child recruitment rates were 33% (n=8) and 75% (n=176). At follow-  
45 up, retention rates were 100% for schools and 97% for children. Outcome measure  
46 completion rates ranged from 63–97%. A preliminary estimate of intervention effectiveness  
47 revealed a mean difference in change in sitting of -30.6 minutes/day (95% CI: -56.42 to -  
48 4.84) in favour of the intervention group, after adjusting for baseline sitting and wear time.  
49 Qualitative measures revealed the intervention and evaluation procedures were  
50 acceptable to teachers and children, except for some problems with activPAL attachment.

51 **Conclusion:** This study provides evidence of the acceptability and feasibility of a sit-stand  
52 desk intervention and evaluation methods. Preliminary evidence suggests the intervention

53 showed potential in reducing children's weekday sitting but some adaptations to the desk  
54 rotation system are needed to maximize exposure. Lessons learnt from this trial will inform  
55 the planning of a definitive trial.

56 **Trial registration:** ISRCTN12915848 (registered: 09/11/16)

57

58 **Keywords**

59 Standing desks; sit-stand desks; primary/elementary school; sedentary behaviour;

60 Bradford; South Asian; children; health inequalities

## 61    **Background**

62    Advances in technology and changes to our environments have resulted in sedentary  
63    behaviour becoming ubiquitous within all settings of daily life. Sedentary behaviour is  
64    distinct from physical (in)activity and is defined as ‘any waking behaviour characterised by  
65    an energy expenditure  $\leq 1.5$  metabolic equivalents (METs) while in a sitting, reclining or  
66    lying posture’ [1]. In the UK, sitting is the most prevalent behaviour exhibited during waking  
67    hours in children, typically accounting for over 65% (~7.5 hours/day) of waking time [2],  
68    with some children reportedly sitting for over 10 hours/day [3]. Sedentary time is  
69    associated with an increased risk of a number of chronic conditions in adults, including  
70    cardiovascular disease, type 2 diabetes and all-cause mortality [4-7]. Whilst evidence of  
71    the associations of sedentary time with increased risk of adiposity/weight gain and  
72    clustered cardiometabolic risk in children is largely restricted to screen time [8], sedentary  
73    behaviours have been shown to increase across key transitions in children’s lives (e.g.  
74    from primary to secondary school) [9] and track into both adolescence [10] and adulthood  
75    [11]. Reducing children’s sitting time may therefore be important for the primary prevention  
76    of chronic diseases in adulthood [12].

77

78    The emergence of an increased cardiometabolic health risk profile in some population  
79    groups is evident during the first decade of life [13]. For example, British South Asian  
80    children have demonstrated higher glycated haemoglobin, fasting insulin and triglyceride  
81    and lower high-density lipoprotein-cholesterol levels compared to white British children as  
82    well as higher levels of fat mass percentage [14, 15]. Higher levels of sedentary behaviour  
83    (ranging between an additional 28 to 39 minutes/day) have also been observed in South  
84    Asian school-aged children (aged 6 – 11 years) in comparison to White British children  
85    [16, 17]. Given the links between sedentary behaviour and cardiometabolic risk [8], early  
86    interventions in such at risk groups may help reduce health inequalities later in life.

88 The environments and social norms that children are exposed to have dominant influences  
89 on their activity behaviour [18]. Given children spend half of their waking hours at school, it  
90 is plausible that the school environment may be a critical influence on their health  
91 behaviour patterns [19-21] and be an appropriate setting for interventions [22], particularly  
92 in relatively deprived locations with higher levels of health inequalities. Indeed, there has  
93 been a growing interest in the use of sit-stand desks (desks which provide children with  
94 the opportunity to alternate their posture between sitting and standing) within the  
95 classroom environment as a tool to reduce sedentary behaviour. Classroom-based  
96 interventions have the potential to target health inequalities because they are accessible to  
97 all children [12].

99 Systematic and narrative reviews of sit-stand desk interventions within the classroom  
100 environment have concluded that this approach shows promise as an effective tool for  
101 reducing children's sitting time and increasing movement. However the majority of studies  
102 included in these reviews have been feasibility trials or small-scale single-school pilot  
103 studies [23-25]. Knowledge of the impact of sit-stand desks on sedentary behaviour,  
104 markers of adiposity and pupil behaviour is currently limited by a lack of randomised  
105 controlled trials (RCTs) [26, 27], and relatively small samples (median sample size across  
106 studies: 45 [24, 26-30]). Furthermore, there has been a limited focus on the acceptability of  
107 this intervention approach in the form of qualitative feedback from teachers and pupils, and  
108 in understanding pupils' experiences and responses (for example, in-class behaviour) to  
109 using sit-stand desks [26, 31, 32]. The above factors will be vital to establish prior to  
110 schools agreeing to the longer-term adoption of this strategy [23, 24, 26]. Limited research  
111 in this area has also been conducted within relatively deprived locations and/or higher-risk  
112 populations, such as South Asian children.

113

114 We have previously demonstrated the feasibility of incorporating sit-stand desks in the  
115 classroom environment over a 9-week period in a small non-randomised controlled study  
116 conducted within one UK primary school with children aged 9-10 years [33]. In this novel  
117 intervention, three standard desks (sitting six children) were replaced with six sit-stand  
118 desks in one classroom. The teacher (who received training in intervention delivery)  
119 rotated the children in the intervention classroom, using naturally occurring breaks  
120 between lessons to do so, to ensure each child was exposed to the desks for at least one  
121 hour/day. Children in a control group (within the same school) continued with their usual  
122 practice, and no environmental changes were made to their classroom. Reductions in total  
123 daily sitting time of 81 mins/day on weekdays (school days) after 9-weeks were seen in the  
124 intervention group. As part of this feasibility work, changes in sitting observed in the  
125 sample were compared to data from a related feasibility study conducted in a primary  
126 school in Melbourne, Australia [33]. Within the Melbourne-based study, every child in the  
127 intervention classroom had a sit-stand desk. No significant differences in reductions in  
128 weekday total sitting time were observed between studies, demonstrating the potential of  
129 this intervention, over the short-term, to reduce children's daily sitting time irrespective of  
130 the different approaches to sit-stand desk provision employed.

131

132 This paper reports the findings of a pilot cluster RCT, conducted in a relatively socially  
133 deprived location within the UK. Rapid increases in sedentary time have been observed in  
134 children aged 11 years and above [34]. This study therefore targeted year 5 classrooms  
135 and involved children aged 9-10 years, with the goal of mitigating the typical rise in  
136 sedentary time seen during the transition into adolescence [9]. The aim of this study was  
137 to examine the feasibility of a protocol for a cluster RCT of a sit-stand desk intervention  
138 within primary school classrooms. If deemed feasible, a fully powered cluster RCT could

139 provide valuable evidence on the effectiveness and cost-effectiveness of a sit-stand desk  
140 intervention within primary school classrooms, incorporating device-based measures of  
141 sitting and activity and a range of health and behaviour-related outcomes. The breadth and  
142 findings of the present study are essential to inform a full trial and the potential longer-term  
143 adoption of sit-stand desks in primary schools. Objectives of this pilot trial included: 1)  
144 evaluating the feasibility and acceptability of recruiting schools and children into the trial; 2)  
145 determining attrition in the trial (schools and children); 3) evaluating the acceptability of the  
146 intervention and randomisation to teachers and children; 4) determining the acceptability  
147 and completion rates of the outcome measures; 5) monitoring the occurrence of any  
148 adverse events of the intervention (or a sit-stand desk); and 6) exploring the potential of  
149 the intervention to reduce children's device-based measurement (activPAL) of weekday  
150 sitting time (the proposed primary outcome in a full trial), and describing the proposed  
151 secondary outcome measures collected at baseline and follow-up (device-based  
152 measurement of physical activity, adiposity, blood pressure, in-class behaviour, and  
153 learning engagement).

154

## 155 **Methods**

### 156 ***Design***

157 The detailed protocol for this pilot trial has been reported elsewhere [12]. The study was a  
158 school-based, two-armed pilot cluster RCT. Individuals (children aged 9-10 years) were  
159 the unit of analysis and schools (clusters) were stratified according to predominant pupil  
160 ethnicity (either >50% White British pupils, or >% South Asian pupils) and randomly  
161 assigned to one of two conditions: 1) six manually adjustable sit-stand desks incorporated  
162 into the classroom environment (intervention condition), or 2) current practice (control  
163 condition). Given the intervention was delivered at the classroom level, rather than  
164 individual level, a cluster design was considered appropriate. Baseline measurements



165 (November 2016) preceded randomisation (December 2016), and the sit-stand desks were  
166 installed into the intervention classrooms following this (February 2017, remaining until  
167 July 2017). An identical set of outcome measurements were taken from all participants  
168 approximately 7-months after baseline testing at the end of the year 5 school term (July  
169 2017). The reporting of this trial follows the CONSORT extension statement for cluster  
170 trials [35] and the CONSORT checklist is provided as supplementary material.

171

## 172 ***Study setting***

173 The study was conducted in primary schools in Bradford, a northern city in England,  
174 chosen as the study location given its ethnic composition (predominantly South Asian and  
175 White British) and high levels of deprivation, health inequalities and childhood morbidity  
176 [36]. Half of all babies born in Bradford are of South Asian origin and 60% are born into the  
177 poorest 20% of the population [36]. The study setting was deemed fundamental in  
178 addressing the important issue of health inequalities, with classroom-based interventions  
179 being accessible to all children [12].

180

## 181 ***Sample size***

182 A recruitment target of eight primary schools, each with at least 15 child participants per  
183 class (approximately 50% of a typical class size) was set, giving a minimum total sample  
184 of 120. This exceeds the target minimum sample size recommended for pilot trials [37]. It  
185 was also assumed that this sample size should be sufficient to provide clear estimates of  
186 recruitment and follow-up to inform a full RCT [12].

187

## 188 ***School and participant recruitment and eligibility criteria***

189 Government-funded primary schools located in the City of Bradford were invited to  
190 participate in the study. Private and designated special educational needs schools and

191 schools with fewer than 25 pupils in year 5 (ages 9-10 years) were not eligible. The aim  
192 was to recruit four schools with predominantly South Asian pupils (>50%) and four with  
193 predominantly White British pupils (>50%). Information on the ethnic composition of the  
194 schools' pupil population was determined using local school census data [12].  
195

196 The following three-stage recruitment process was adopted for schools: 1) head  
197 teachers/senior teachers were sent an email detailing the study, which included a copy of  
198 an Information Sheet for Schools; 2) two days after sending the email, the schools were  
199 contacted via telephone and the reception team were asked to confirm receipt of the email;  
200 3) a follow-up telephone call was made to establish the schools' interest or otherwise in  
201 participating in the study. A designated lead teacher was identified for each interested  
202 school who was then given full details of the study and what their involvement would entail.  
203

204 Consenting schools were asked to nominate a year 5 class and were provided with  
205 invitation packs for the parents/guardians of children within these classes. All children  
206 within participating classes were eligible to take part in the evaluation. The invitation pack  
207 contained a detailed Information Sheet for Parents/Guardians, an opt-in consent form for  
208 the parent/guardian to complete and return if they were happy for their child to participate  
209 in the evaluation, and an Information Sheet for Children. Completed consent forms were  
210 returned by pupils to their teacher, who informed the research team of the children who  
211 were to be involved in the evaluation measures. At the beginning of the baseline  
212 measurement session, all methods were fully explained to children by a member of the  
213 research team at which time they were asked to provide verbal and written assent. This  
214 was requested again at the start of the follow-up measurement sessions.  
215  
216

217 ***The ‘Stand Out in Class’ intervention***

218 Six height-adjustable sit-stand desks (LearnFit, Ergotron Inc, USA) were placed in a year 5  
219 classroom (replacing three standard desks sitting 6 children) in each intervention school  
220 for two school terms, spanning 4.5 months. The research team supported teachers in the  
221 development of a classroom rotation plan to ensure all children in their class were exposed  
222 to the sit-stand desks for at least one hour/day on average across the week. Stools or  
223 chairs remained in the classroom and while children were free to choose whether they sat  
224 or stood when using the sit-stand desks, they were encouraged to stand by teachers, as  
225 well as through the use of nudge prompts displayed on the desks and standing champions  
226 (i.e. one child in a class who was given the responsibility of reminding the teacher about  
227 the rotation plan) (see Figure 1)[12].

228

229 Teachers and pupils in the intervention classrooms received training on sit-stand desk use  
230 by the research team and teachers also received a ‘Professional Development Manual’  
231 containing information on the health benefits of reducing prolonged sitting and on correct  
232 posture when standing at the desks. The teacher manual and training focussed on  
233 encouraging adoption of the intervention, targeting key barriers and facilitators to sit-stand  
234 desk use. These were identified from: our previous work [33, 38]; the Capability,  
235 Opportunity, and Motivation to perform a Behaviour (COM-B) model within the Behaviour  
236 Change Wheel [39]; and the Theoretical Domains Framework [40] (e.g. self-efficacy,  
237 motivation and knowledge). Standardised behaviour change techniques (e.g. goal setting,  
238 instruction) [41] were also used during the training with teachers and pupils [12]. Further  
239 details of the intervention, including an overview of the intervention components and  
240 potential barriers, solutions, and hypothesised mediating processes informed by the above  
241 theoretical frameworks are reported elsewhere [12]. A logic model for the Stand Out in  
242 Class intervention, applicable for a definitive trial, is presented in Figure 1.

*Insert Figure 1 about here*

### ***The usual practice control arm***

To compare the effects of the intervention against usual practice (i.e. the provision of standard classroom desks), schools assigned to the control arm were requested to continue with their usual practice and lesson delivery; no environmental changes were made to their classrooms [12].

### ***Allocation to treatment groups***

Schools were stratified based on the ethnic composition of their pupils. Following baseline measurements, schools within each stratum were randomised into the two study arms using an allocation ratio of 1:1, employing a randomisation list in SAS software, by an independent statistician at the Leicester Clinical Trials Unit (CTU). Two schools with predominantly South Asian pupils (>50%) and two schools with predominantly White British pupils (>50%) were randomised into the intervention and control arms (4 schools in each arm).

### ***Outcome measurements***

The primary outcomes of this pilot trial were the feasibility and acceptability of the research procedures (including recruitment, data collection, randomisation, acceptability of the intervention, retention, and the presence of any adverse events) to inform the planning of a full RCT. A detailed process evaluation describing teachers' and children's experiences of the intervention is reported elsewhere [42]. Study uptake was monitored by recording the number of schools and pupils approached, and the number agreeing to participate (objective 1). Withdrawal rates of schools and children were recorded (objective 2). The acceptability of recruitment (objective 1), the intervention and randomisation (objective 3), and the acceptability of outcome measures (objective 4) were determined via focus groups

269 with children and interviews with teachers. Furthermore, completion rates of the outcome  
270 measures were recorded (objective 4), along with the occurrence of any study-related  
271 adverse events (objective 5).

272

273 Interviews with teachers and focus groups with children from both trial arms were  
274 conducted approximately 1 month following randomisation to explore the acceptability of  
275 recruitment (example question: *'What did you think about the way that you were asked to*  
276 *take part in the Stand Out in Class Study?'*), randomisation (example question: *'What did*  
277 *you think about being randomised to one of the 2 school groups in the study*  
278 *[control/intervention]?'*), and the measurement instruments (example question to children:  
279 *'What was your view about wearing the thigh worn device for 7 days?'*). The acceptability  
280 of the intervention was determined through a further set of interviews (with teachers) and  
281 focus groups (with children) from the 4 intervention schools during the final month of the  
282 intervention. An example question to intervention teachers and children included: *'What*  
283 *has been your experience so far of the sit-stand desks being part of your classroom?'*.

284

285 Four male (3 control group, 1 intervention) and 4 female (1 control, 3 intervention)  
286 teachers participated in the study. A total of 43 children, 22 boys and 21 girls, took part in  
287 the focus groups following randomisation (8 focus groups were conducted, 1 per school)  
288 and 24 children, 10 boys and 14 girls, participated in the focus groups towards the end of  
289 the trial (4 intervention schools only). Teachers selected children in their class for  
290 participation in the focus groups. Within the intervention classes, there may have been  
291 some overlap between children participating in the first and second focus groups (at the  
292 end of the trial). All interviews and focus groups, across both phases, used semi-structured  
293 topic guides to ensure consistency. The focus group topic guides were written in child  
294 friendly language. All interviews and focus groups were audio-recorded digitally.

295

296 Device-based sitting was measured for 7 consecutive days during each measurement  
297 period using the activPAL3 micro accelerometer (PAL Technologies, UK). This device has  
298 been shown to provide a valid measure of posture in children [43]. All activPALs were  
299 initialised and downloaded using manufacturer proprietary software (activPAL Professional  
300 v.7.2.32) and data were processed using the freely available ProcessingPAL Software  
301 (<https://github.com/UOL-COLS/ProcessingPAL>, version 1.1, University of Leicester,  
302 (Leicester UK)). The activPAL3 was waterproofed (using a nitrile sleeve and  
303 hypoallergenic Hypafix [BSN Medical] dressing) and participants were requested to wear  
304 the device continuously (24 hours/day) on the anterior aspect of their right thigh. The  
305 device was attached using Hypafix dressing. Participants were provided with a brief diary  
306 during each monitoring period in which they were requested to document time in bed and  
307 any periods of non-wear [12]. Periods of prolonged non-wear and time in bed were  
308 removed from the data using the default algorithm rules within Processing PAL [44].  
309 Briefly, the algorithm searches within event files (created in the activPAL Professional  
310 software) to identify prolonged bouts of behaviour (sitting, standing) within a noon-noon  
311 period. If they meet the criteria they are coded as time in bed/non-wear (no distinction). To  
312 accommodate fragmented sleep patterns, the algorithm searches around these identified  
313 bouts for other prolonged bouts of behaviour occurring after brief upright activity. If they  
314 meet the criteria, the identified bouts and the upright activity are also coded as time in  
315 bed/non-wear. Once time in bed and non-wear were excluded, a day was considered  
316 valid if it consisted of  $\geq 8$  hours of waking wear data,  $< 95\%$  of time spent in any one  
317 behaviour (e.g., sitting, standing, or stepping) and  $\geq 500$  single leg steps (i.e.,  $\geq 1000$  steps)  
318 [44]. Due to the exploratory nature of this study, children were included in the analysis  
319 relating to objective 6 (exploring the potential of the intervention to reduce children's

320 weekday sitting time) if they had worn the activPAL for at least 8 hours on at least 1  
321 weekday at baseline and follow-up.

322

323 Proposed secondary outcomes for a future full trial included device-based measured  
324 physical activity, using the ActiGraph GT3X+ accelerometer (ActiGraph, Pensacola, FL)  
325 worn on an elasticated belt at the waist continuously (24 hours/day) for 7 consecutive  
326 days, concurrently with the activPAL. The feasibility of collecting ActiGraph data, in  
327 addition to activPAL data, was examined to inform a full trial, where this device could be  
328 used as a secondary outcome to examine any positive or negative (i.e. compensatory)  
329 effects of the intervention on physical activity either during or after school hours.

330 ActiGraphs were initialised to record data at 60 Hz. The devices were initialised and  
331 downloaded using ActiLife version 6.13.3, and the data (reintegrated into 15 second  
332 epochs) were processed using specifically developed and commercially available software  
333 (KineSoft version 3.3.20, Loughborough UK). Time spent in light (26 – 573 counts per 15  
334 second epoch) and moderate-to-vigorous intensity ( $\geq 574$  counts per 15 second epoch)  
335 activity were determined using the Evenson cut-points [45]. Due to the 24-hour wear  
336 protocol of the ActiGraphs, a blanket removal of sleep time between 11pm and 5.59am  
337 was undertaken when processing these data. However, to identify periods of sleep and/or  
338 non-wear occurring outside of this time period (i.e. after 6am and before 11pm), the 3-axis  
339 acceleration data from the ActiGraph were used to detect periods of no movement. If these  
340 periods exceeded 20 minutes of zero counts, then this additional period was excluded as  
341 non-wear/sleep time. The same wear time criteria as applied to the activPAL data (a  
342 minimum of 8 hours of wear on at least one weekday) was also applied to the ActiGraph  
343 data.

344

345 At each measurement point children's height and body mass (without shoes) were  
346 measured directly using standard procedures by trained research staff. Body composition  
347 was assessed using bio-impedance analysis scales, suitable for use with children (Tanita  
348 DC-360S). Blood pressure was measured from the left arm after at least a five minute  
349 period of quiet sitting using a semi-automated recorder (Omron HEM-907) with a  
350 paediatric cuff, in accordance with current recommendations [46]. Three assessments  
351 were taken with each measurement separated by a two-minute rest period and the mean  
352 systolic and diastolic blood pressures recorded from the second and third assessments  
353 were calculated.

354

355 The impact of the intervention on participants' behaviour was assessed using the  
356 Strengths and Difficulties questionnaire [47], a measure of pro-social behaviour, emotional  
357 symptoms, conduct problems, hyperactivity and peer problems, completed by teachers at  
358 baseline and follow-up. The questionnaire consists of 25 items, with five items per scale,  
359 which receive a score from 0 to 2. A total difficulties score is calculated by summing the  
360 scores from the first four scales, with higher scores indicating increased behavioural  
361 difficulties [47]. In addition, children self-reported their engagement and disaffection with  
362 their own learning via the Engagement Versus Disaffection with Learning questionnaire  
363 [48]. This questionnaire assesses behavioural engagement and behavioural disaffection,  
364 using five items each, along with emotional engagement, using five items, and emotional  
365 disaffection, using 12 items. Each item is scored on a 1 to 4 scale, with higher values  
366 indicating increased levels of engagement and reduced disaffection. Mean scores are  
367 calculated across the two engagement and disaffection categories to provide an overall  
368 indication of engagement and disaffection levels [49].

369



370 Children furthermore completed the Paediatric Quality of Life Inventory (PEDS-QL) [50]  
371 and EuroQol 5-dimension Youth (EQ-5D-Y) [51] at each measurement point to provide a  
372 measure of self-reported quality of life to inform an economic analysis in a full trial. Basic  
373 demographic information (sex, age, ethnicity) were reported by children at baseline. Full  
374 details of all measurement instruments, along with information on their validity has been  
375 reported elsewhere [12].

376

## 377 ***Quantitative and qualitative analyses***

### 378 *Trial feasibility and acceptability*

379 As this was a pilot trial, the primary analyses (the purpose of which was to assess the  
380 feasibility of conducting a cluster RCT of a sit-stand desk intervention within primary  
381 school classrooms) mainly utilised descriptive statistics summarising: the number of  
382 schools approached, the number agreeing to participate, and the proportion of children  
383 within each school with parental/guardian consent, and giving their assent, to participate in  
384 the study evaluation (objective 1); retention rates (schools and children) (objective 2);  
385 outcome measure completion rates and compliance (objective 4); and the documentation  
386 of any study-related adverse events (objective 5).

387

388 The acceptability of recruitment (objective 1), randomisation and the intervention (objective  
389 3), along with the acceptability of the outcome measures (objective 4) were determined  
390 through qualitative analyses of the pupil focus groups and teacher interview data. Audio  
391 recordings were transcribed verbatim with anonymisation of all personal data. To address  
392 the objects within the present paper, sample quotes which reflect common responses  
393 across the questions asked are provided (a detailed process evaluation is reported  
394 elsewhere[42]). Extracts from the focus groups and interviews are labelled to indicate the

395 participant (Child/Teacher), group (I = intervention, C = control) and school (number 1-4  
396 within each trial arm).

397

398 *The potential of the intervention to reduce children's weekday sitting time, and a summary*  
399 *of the proposed secondary outcomes for inclusion in a full trial (objective 6)*

400 An objective of this study was to examine the potential of the intervention to reduce  
401 children's weekday sitting time (the proposed primary outcome in a full trial). As the  
402 number of clusters was low, cluster summary statistics were used rather than multi-level  
403 modelling [52, 53]. A weighted linear regression model compared the change in mean  
404 weekday sitting time between follow-up and baseline between control and intervention arm  
405 participants. The model was adjusted for baseline total daily sitting time on school days  
406 and average weekday wear time across the two measurement points. Subsequent models  
407 adjusted for the season in which the baseline and follow-up measures were taken. Since  
408 the variables in the regression model reflect cluster means rather than individual  
409 observations, an analytically weighted least squares method of estimation was used,  
410 where cluster sizes were the weights. The results from this analysis should, however, be  
411 treated as preliminary and interpreted with caution given the lack of statistical power [54,  
412 55]. Statistical analyses were undertaken using Stata version 15.1 (StataCorp, Texas,  
413 USA), and were validated by an independent trial statistician at the Leicester CTU.

414

415 Descriptive statistics were calculated to summarise the proposed secondary outcomes  
416 (device-based measured time spent in light intensity and moderate-to-vigorous intensity  
417 activity on weekdays, adiposity, blood pressure, behaviour, and learning engagement)  
418 measured at baseline and follow-up.

419

420

## 421 **Results**

### 422 ***Trial feasibility and acceptability***

423 Twenty-four eligible schools were approached and of these the target number of eight  
424 schools consented to participate, with the overall recruitment rate being 33% (95% CI: 16  
425 to 55%). Twelve schools did not consent to join the study (50%) and four did not respond  
426 to the initial email (17%). All eight participating schools completed the trial (100%  
427 retention). Data from the 2016-2017 school census [56] show that the proportion of  
428 children eligible for free school meals was similar across the recruited schools and the  
429 declined schools (mean: 17.1% [range: 2.3%, 26.4%] vs. 17.4% [9.6%, 28.5%]), with these  
430 values being higher than the national average of 14.8% in 2016-2017.

431

432 The proportion of pupils at the eight schools with parental consent to participate in the trial  
433 evaluation was 75% (176 out of 234), exceeding the target minimum sample of 120 [12].  
434 At follow-up, retention of participating children was 97% (170 out of 176). A CONSORT  
435 flow diagram is shown in Figure 2. Two pupils in the control group were unable to provide  
436 follow-up measures as they were absent from school on the days they were taken. Three  
437 children (1 control, 2 intervention) moved away from the area during the study and hence  
438 changed schools. One control group participant withdrew their assent prior to the follow-up  
439 measures. The demographic characteristics of the participating children at baseline are  
440 shown in Table 1.

441 *Insert Figure 2 about here*

442

443

444

445

**Table 1.** Demographic characteristics of the participating children, by group and total sample.

		Control	Intervention	Overall
		(n = 90)	(n = 86)	(n = 176)
Sex, n (%)	Male	50 (55.6%)	48 (55.8%)	98 (55.7%)
	Female	44 (44.4%)	38 (44.2%)	78 (44.3%)
Ethnicity, n (%)	White British	18 (20.0%)	45 (52.3%)	63 (35.8%)
	South Asian	59 (65.6%)	26 (30.2%)	85 (48.3%)
	Other	13 (14.4%)	15 (17.4%)	28 (15.9%)
Age	Mean (SD)	9.3 (0.5)	9.3 (0.4)	9.3 (0.5)

Completion rates of the proposed outcome measures for inclusion in a full RCT at baseline and follow-up are shown in Table 2. The table also displays the proportion of children providing valid activPAL and ActiGraph data on at least 1, 2, 3, 4 and all 5 weekdays.

464 **Table 2.** Total sample outcome measure compliance and completion rates at baseline and  
 465 follow-up

	Baseline	Follow-up	Both baseline and follow-up
activPAL data on weekdays*			
≥1 valid day	80.1%	76.1%	63.1%
≥2 valid days	74.4%	66.5%	51.7%
≥3 valid days	65.3%	53.4%	39.2%
≥4 valid days	54.5%	42.6%	27.3%
5 valid days	18.2%	16.5%	5.7%
ActiGraph data on weekdays*			
≥1 valid day	94.3%	87.5%	83.5%
≥2 valid days	89.8%	78.4%	73.3%
≥3 valid days	85.2%	65.3%	58.0%
≥4 valid days	75.0%	50.0%	42.6%
5 valid days	25.6%	11.4%	5.1%
Anthropometric measures	98.9%	95.5%	94.3%
Body composition	98.9%	94.9%	93.8%
Blood pressure	77.8%	89.8%	70.5%
Engagement vs Disaffection with Learning (child reported)	97.7%	96.0%	93.8%
Strength and Difficulties questionnaire (teacher reported)	91.5%	94.9%	90.3%
PEDS-QL	83.0%	93.2%	83.0%
EQ-5D-Y	94.6%	94.6%	94.6%

466 \*A valid day for the activPAL and ActiGraph constituted at least 8 hours of wear on a  
 467 weekday  
 468

469 No serious adverse events were reported throughout the duration of the trial. Specifically,  
470 there were no adverse effects associated with the intervention that related to  
471 musculoskeletal discomfort and/or disruption to the classroom or to reported learning.

472

473 All eight teachers expressed high satisfaction with the recruitment protocol, with all stating  
474 the study had been clearly explained:

475 *“Yeah, it was very well explained and the ideas and the concept behind what you*  
476 *were doing, so I had no hesitation accepting really.” (Teacher, C1)*

477

478 Teachers also commented that the recruitment approach was appropriate and suitable for  
479 children:

480 *“It worked well. I think you got quite a good uptake...as a class, so obviously what*  
481 *you were sending out and the conversations you were having with the children got*  
482 *them quite enthused. I think with them, with the children they’re doing something*  
483 *scientific because they all sort of really love science, the idea of doing something*  
484 *scientific with scientists is like “yay!” So they jumped on that.” (Teacher, C2).*

485

486 Children across all focus groups reported that recruitment had been positive for them, the  
487 study made clear, and that everyone had a choice to participate:

488 *“It was good because once I got the letter, I didn’t understand what it was.*  
489 *[Researchers] told us about the letter and our teachers told us about it and told us*  
490 *to tell our mum if we want to go or not because you first need permission off your*  
491 *mum, and that’s why it was a good process because you got told three times.”*  
492 *(Child, I1).*

493

494 *"It's more like you get to choose to take part and if you don't want to then it doesn't*  
495 *matter."* (Child, I3).

496

497 When asked about the acceptability of randomisation, all teachers and children expressed  
498 a clear understanding of why randomisation had occurred. Whilst control group teachers  
499 and children were disappointed not to have worked with the sit-stand desks, they  
500 considered their participation in the trial to be positive and important:

501 *"Well, I completely understand why you need to have a control. You know, we teach*  
502 *the children, that certain investigations need a control, you need something to*  
503 *compare it against..."* (Teacher, C3).

504

505 *"Because then you can look at the schools that have the tables and the schools that*  
506 *didn't and look at the difference on health."* (Child, I3).

507

508 With regards to the acceptability of the activPAL (as a primary outcome measure for a full  
509 trial), the most common theme identified from the responses related to issues with the  
510 medical dressing used (Hypafix® transparent) to attach the monitor. This reportedly caused  
511 a minority of children to suffer from itchiness, soreness and discomfort, and led to some  
512 class disruption:

513 *"Yeah, it was a bit faffy. Some of the children did complain about getting a bit of a*  
514 *rash, but they like to complain anyway, so it was a bit... I don't want to use the word*  
515 *chaotic, but that was more to do with the fact that the kids were constantly*  
516 *interested by them so they were focused on them..."* (Teacher, I1)

517

518 However, other teachers did not perceive the medical dressing to be particularly  
519 problematic as only a few children had been affected:

520           *“...there were only a few complaints [about the dressing]...”, (Teacher, C2)*

521

522           *“Only a couple of them had a little reaction to it.” (Teacher, I4)*

523

524   During the focus groups with children, 10 out of 43 reported feeling some discomfort  
525   related to the activPAL:

526           *“When you tried to take it off it really hurt.” (Child, C3)*

527

528           *“When I took it off I had a bit of like a little rash or a few spots, from the underneath*  
529           *because my leg got quite sweaty.” (Child, C1).*

530

531   In contrast to the activPAL, the ActiGraph was regarded as a more acceptable device for  
532   children to wear by all teachers and most children (38/43):

533           *“It didn’t really annoy me at all and it felt like nothing was even there.” (Child, C4)*

534

535   The focus groups and interviews with intervention children and teachers conducted  
536   towards the end of the study period revealed that the intervention was generally well  
537   accepted by children and teachers. All teachers expressed that the desks had become  
538   part of their classroom, and that any initial concerns they had had regarding the desks  
539   causing a distraction had not materialised:

540           *“Yeah, well for me I’m now used to them so before, I think for the first month or so, I*  
541           *was kind of looking at them as to how would they work, how well would they work*  
542           *with the children, would it just be a distraction for them, but now it’s, it’s kind of just*  
543           *the norm for the children, and we’re kind of, we’re used to them and every week*  
544           *when we rotate round we, we just do it steadily.” (Teacher, I2).*

545



546 The children felt having the desks in their classroom had been very positive, with key  
547 themes including changing behaviour for the better, liking having the option to stand, and  
548 appreciating the increased personal working space afforded by the desks:

549 *“they really change boys’ behaviours because some boys, not me, are fidgety so it’s*  
550 *good for them to stand up.”* (Child I4)

551

552 *“I like it because, like, every time you don’t feel comfortable while sitting down, you*  
553 *could just stand up and then you might feel more comfortable.”* (Child, I3).

554

555 *“It’s like it’s a lot better than our tables because when we do our work, sometimes*  
556 *Miss says, sit down to do our work but then now with the stand-up-sit-down tables*  
557 *we can stand up more because I like working when I stand up especially when it’s*  
558 *stuff like art and stuff like that where you have to draw.”* (Child, I4).

559

560 *“I liked it because it was only for one person to sit on, for each table. Because*  
561 *normally, when we have to share a table, there’s not enough space.”* (Child, I2).

562

### 563 ***The potential of the intervention to reduce children’s weekday sitting time***

564 An objective of this pilot trial was to examine preliminary evidence of the effectiveness of  
565 the intervention in changing mean weekday sitting time, as the intervention was school  
566 based. Total school day/weekday sitting time was chosen as this encompasses school  
567 hours and out of school hours, and factors in any potential compensatory effects of the  
568 intervention (i.e. increases in sitting after school). Table 3 displays the descriptive statistics  
569 for all activPAL variables recorded throughout waking hours on weekdays for the control  
570 and intervention groups.

571

**Table 3.** Descriptive statistics for the activPAL variables measured throughout waking hours on weekdays.

Waking hours on weekdays	Baseline		Follow-up		Change	
	Control	Intervention	Control	Intervention	Control	Intervention
	(n = 57)	(n = 52)	(n = 57)	(n = 52)	(n = 57)	(n = 52)
Wear time (min/day)	836.3 (88.5)	843.8 (47.8)	830.9 (78.6)	835.4 (64.2)	-3.7 (121.6)	-8.4 (62.3)
Time spent sitting (mins/day)	520.1 (83.6)	514 (61.5)	504.4 (94.0)	472.0 (73.5)	-15.2 (107.5)	-42.0 (76.6)
Time spent standing (mins/day)	179.9 (58.6)	195.4 (38.7)	176.5 (45.7)	197.1 (49.4)	-3.0 (50.2)	1.6 (52.0)
Time spent stepping (min/day)	136.3 (44.9)	134.4 (30.4)	150.0 (42.1)	166.4 (41.9)	14.4 (44.8)	32.0 (41.1)
Percentage of wear time spent sitting (%)	62.4 (8.8)	60.9 (5.9)	60.5 (8.6)	56.5 (8.2)	-2.0 (8.7)	-4.3 (8.6)
Percentage of wear time spent standing (%)	21.4 (6.3)	23.2 (4.5)	21.5 (6.1)	23.6 (5.7)	0.1 (5.9)	0.4 (5.8)
Percentage of wear time spent stepping (%)	16.2 (4.7)	15.9 (3.5)	18.1 (4.8)	19.9 (4.6)	1.9 (4.6)	3.9 (4.6)
Number of sit to stand transitions	102.5 (28.7)	106.4 (23.6)	104.1 (26.5)	106.2 (21.4)	1.6 (25.0)	0.2 (20.5)
Number of days worn	3.7 (1.3)	3.5 (0.9)	3.2 (1.2)	3.5 (1.4)	-0.5 (1.4)	0.0 (1.8)

Data are presented as the mean (SD). This table includes data from participants who wore the activPAL device with a minimum valid wear time of 8 hours each day on at least one weekday at baseline and at 7-months follow-up.

578 The weighted linear regression model applied revealed the mean difference in change in  
579 sitting time was -30.6 minutes/day (95% CI: -56.42 to -4.83) for the intervention group,  
580 relative to the control group. The addition of baseline season of activPAL data collection to  
581 the weighted linear regression model did not affect the difference in sitting time between  
582 groups. When follow-up season was included in the model the adjusted difference in sitting  
583 time between groups was -26.64 minutes/day (95% CI: -73.08 to 19.79).

584

585 Table 4 displays the descriptive statistics for all ActiGraph variables recorded throughout  
586 waking hours on weekdays for the control and intervention groups. Both groups  
587 demonstrated small changes in light intensity physical activity and moderate-to-vigorous  
588 intensity physical activity (MVPA) over the follow-up period. Descriptive statistics for the  
589 anthropometric, blood pressure and questionnaire measures (Engagement and  
590 Disaffection with Learning and the Strengths and Difficulties questionnaire) collected from  
591 participants at baseline and follow-up are shown in Table 5. The changes seen in the  
592 anthropometric measurements over the follow-up period are reflective of typical growth-  
593 related changes in children of this age. There were no noticeable between-group  
594 differences in the mean changes in learning engagement and disaffection scores over the  
595 trial period, and a small decrease in the total difficulties score (indicating improved  
596 behaviour) in the intervention group relative to the control group over the follow-up period.

597

598

599

600

601

602

**Table 4.** Descriptive statistics for the ActiGraph variables measured throughout waking hours on weekdays.

Waking hours on weekdays	Baseline		Follow-up		Change	
	Control	Intervention	Control	Intervention	Control	Intervention
	(n = 74)	(n = 72)	(n = 74)	(n = 72)	(n = 74)	(n = 72)
Wear time (min/day)	885.1 (90.5)	882.6 (84.5)	827.7 (134.1)	852.9 (106.8)	-57.4 (125.9)	-29.7 (118.0)
Time spent in light PA (mins/day)	378.2 (61.9)	383.5 (68.6)	364.3 (81.2)	392.7 (70.8)	-13.9 (74.4)	9.3 (78.3)
Time spent in MVPA (min/day)	40.0 (20.5)	37.4 (17.9)	40.7 (30.9)	45.7 (24.7)	0.7 (24.5)	8.3 (20.0)
Percentage of wear time spent in light PA (%)	43 (6.4)	43.4 (6.2)	44.0 (6.9)	46.0 (6.0)	1.1 (5.5)	2.6 (5.6)
Percentage of wear time spent in MVPA (%)	4.6 (2.3)	4.3 (2.1)	5.0 (3.8)	5.4 (2.7)	0.5 (2.8)	1.1 (2.2)
Number of days worn	3.8 (1.4)	3.6 (1.3)	2.8 (1.5)	3.2 (1.6)	-1.0 (1.3)	-0.4 (1.3)

Data are presented as the mean (SD). This table includes data from participants who wore the ActiGraph device with a minimum valid wear time of 8 hours each day on at least one weekday at baseline and at 7 months follow-up.

615 **Table 5.** Anthropometric, blood pressure and questionnaire measurements

	Baseline		Follow-up		Change	
	Control (n = 90)	Intervention (n = 84)	Control (n = 85)	Intervention (n = 83)	Control (n = 85)	Intervention (n = 81)
Height (cm)	140.5 (6.6)	138.3 (6.2)	144.0 (6.8)	141.3 (6.4)	3.3 (1.7)	2.9 (1.0)
Body mass (kg)	36.3 (9.5)	35.0 (7.8)	39.2 (10.6)	37.7 (8.7)	3.0 (1.7)	2.7 (1.7)
Percent body fat – Girls <sup>§</sup>	24.4 (8.4)	23.6 (8.1)	23.7 (9.1)	25.0 (8.3)	-0.7 (2.1)	0.5 (2.8)
Percent body fat - Boys <sup>§</sup>	20.6 (8.9)	19.9 (6.9)	20.7 (8.9)	19.0 (6.6)	0.4 (2.6)	-0.9 (2.4)
BMI (kg/m <sup>2</sup> )	18.2 (4.0)	18.2 (3.3)	18.7 (4.1)	18.8 (3.5)	0.6 (0.8)	0.6 (0.7)
Systolic blood pressure (mmHg)*	102.5 (11.8)	102.8 (15.2)	107.3 (11.7)	110.5 (11.2)	5.1 (15.8)	10.2 (17.8)
Diastolic blood pressure (mmHg)*	66.1 (10.2)	67.3 (14.1)	66.3 (9.5)	68.4 (9.7)	0.2 (12.1)	2.4 (16.2)
Engagement and Disaffection with Learning questionnaire sub-scale scores (child reported)						
	Control (n = 90)	Intervention (n = 82)	Control (n = 86)	Intervention (n = 83)	Control (n = 86)	Intervention (n = 80)
Overall Engagement	3.4 (0.5)	3.4 (0.5)	3.3 (0.6)	3.3 (0.5)	-0.1 (0.6)	-0.1 (0.5)
Overall Disaffection	3.1 (0.7)	3.1 (0.7)	3.2 (0.7)	3.1 (0.6)	0.1 (0.7)	0.0 (0.6)
Strengths and Difficulties questionnaire (teacher reported)						
	Control (n = 83)	Intervention (n = 78)	Control (n = 83)	Intervention (n = 84)	Control (n = 81)	Intervention (n = 78)
Total difficulties score	6.2 (5.7)	9.2 (7.6)	6.9 (6.0)	7.8 (6.6)	0.6 (4.6)	-1.3 (4.5)

616 Data are reported as the mean (SD). <sup>§</sup>Percent body fat sample sizes: girls, control n = 40,

617 intervention n = 35; boys, control n = 50; intervention n = 49. \*The sample size for the

618 change in blood pressure measurements reduced to 54 control participants and 49  
619 intervention participants.

620

## 621 **Discussion**

622 The purpose of this study was to undertake a pilot cluster RCT to test the feasibility and  
623 acceptability of conducting and evaluating a school-based sit-stand desk intervention. The  
624 findings confirmed that recruitment and attrition rates were acceptable to support  
625 progression to a full trial, most outcome measures were acceptable, and the intervention  
626 was well received. However, improvements to compliance with protocols for assessing the  
627 proposed primary outcome (activPAL-determined sitting time) are needed. Furthermore,  
628 preliminary evidence demonstrated the potential of the intervention in reducing children's  
629 weekday sitting time, although the changes observed were not as large as those seen  
630 previously within the same setting within a 9-week non-randomised controlled study  
631 conducted in just one school [33].

632

633 The uptake into the study by schools (33% of those approached) is similar to recruitment  
634 rates seen in other primary school-based interventions located in the same region [57] and  
635 elsewhere in England [58]. Whilst all eight recruited schools were located predominantly in  
636 urban areas within the Bradford metropolitan district, the study was effective in recruiting a  
637 diverse range of schools in terms of the ethnic composition of their pupils within a relatively  
638 deprived setting. Within the participating schools, parental consent and pupil assent to  
639 participate was obtained for 75% (n = 176) of eligible pupils, exceeding our target  
640 minimum sample size (120 participants) [12]. Furthermore, school and participant retention  
641 rates within the trial were high (100% and 97% respectively). Overall, these findings  
642 demonstrate the feasibility of recruiting and retaining schools and participants into a  
643 school-based sit-stand desk RCT and suggest good interest and recognition of the

644 importance of the study by participating schools. Whilst schools have been identified as  
645 important environments for health promoting interventions [22], the challenges of recruiting  
646 schools and children, particularly via opt-in consent procedures (as adopted herein), and in  
647 retaining participants, have been highlighted [59].

648

649 Most outcome measures were regarded as acceptable by children and teachers. Of the  
650 physiological measures, lower compliance rates were seen for blood pressure, with some  
651 children stating during the assessments that they found this measure uncomfortable.  
652 Whilst modest (63%), the proportion of children providing valid activPAL data in the  
653 present study is higher than that observed previously in the same study setting [33], and  
654 similar to that in a recent sit-stand desk RCT in Belgian children [26]. The main issue faced  
655 was with the medical dressing (Hypafix [BSN Medical]) used to attach the activPAL, with  
656 this reportedly causing irritation on the leg for some children. In the present study we  
657 adopted a 24-hour wear protocol with the anticipation that the hypoallergenic dressing  
658 would stay on the skin for a number of days, and not require children to frequently remove  
659 the device (and dressing), with the purpose of reducing participant burden. However, this  
660 did not prove to be very effective as a number of children requested additional medical  
661 dressing throughout the monitoring periods to enable them to re-attach the activPAL after  
662 removal. Other researchers have enclosed the activPAL in a small pocket in an adjustable  
663 elasticised belt worn at the mid-anterior position of the thigh throughout waking hours only,  
664 removing it for water-based activities. This approach has been used successfully (85%  
665 compliance) in cross-sectional research [60] and is worth exploring ahead of a full trial.  
666 Evidently, further research is needed on the attachment options for the activPAL in  
667 children to improve compliance. In comparison to the activPAL, compliance rates for the  
668 waist-worn ActiGraph were higher (83%) and this device was reasonably well accepted by  
669 children.

670

671 The intervention was well received by teachers and children, and towards the end of the  
672 intervention teachers commented on how the desks were regarded as part of the norm  
673 within their classrooms. This positive finding suggests teachers are both prepared and  
674 capable of adapting their teaching style and willing to make modifications to their  
675 classroom environments. Some children reported that they felt the desks improved  
676 behaviour within the classroom. These findings are consistent with others who have  
677 concluded that sit-stand desks can be introduced into the classroom environment without  
678 having a negative impact on student learning, behaviour, musculoskeletal comfort, or  
679 causing classroom disruption [28, 29, 31, 61, 62]. The absence of any negative impacts of  
680 sit-stand desks on these outcomes are likely to be of particular interest to schools  
681 considering adopting these desks in the future. Further, the potential positive effects  
682 observed within this study on pupil behaviour and increases in pupil autonomy (having the  
683 choice of sitting or standing) are even more encouraging and support further testing of this  
684 intervention.

685

686 Preliminary analyses demonstrated the potential of the intervention in reducing children's  
687 weekday sitting time, with the intervention group reducing their total weekday sitting time  
688 by more than 30 minutes/day relative to the control group. No data currently exist in  
689 children to inform the magnitude of a reduction in sitting time needed to bring about  
690 changes in health markers. This information will be vital in the future to inform public health  
691 messaging. Data from adults however have indicated that reallocating just 30 minutes of  
692 sedentary time per day to light movement is associated with a 2–4% improvement in  
693 cardiometabolic biomarkers [63]. An earlier meta-analysis of RCTs and non-RCTs  
694 delivered in the school or home environment reported an overall decrease in children's  
695 sedentary behaviour of 18 mins/day [64]. The preliminary findings from this study hold



696 promise, therefore, and support the need for further RCTs examining the impact of sit-  
697 stand desks in the classroom environment. The reduction in sitting time observed in the  
698 current pilot RCT is also greater than that reported in a recent sit-stand desk RCT  
699 conducted in primary school children in Belgium where, relative to the control group, the  
700 intervention group experienced a reduction in daily sitting of 13.5 minutes/day over the 8-  
701 12 week intervention period [26]. In the Belgian study however, only three sit-stand desks  
702 were placed in the intervention classrooms and pupils were exposed to these desks for an  
703 average of 60 minutes/week, which likely explains the differences in findings.

704

705 When a bank of sit-stand desks are included within the classroom environment, as in the  
706 present study, the Belgian study [26] and in our earlier study [33], the creation and  
707 successful implementation of a regular rotation plan is important in order to maximise pupil  
708 exposure to the sit-stand desks. In our previous small study, the teacher was very effective  
709 in rotating pupils daily around the classroom to ensure equal exposure to the desks of  
710 approximately one hour/day on average, and this led to a large reduction in mean  
711 weekday sitting time (81 mins/day). In the present study, our intervention instructed  
712 teachers to rotate children daily, however some intervention teachers trialled different  
713 rotation options which may have reduced the overall exposure to the desks and the  
714 subsequent impact of the intervention and explain the differences between our study  
715 findings. This has been explored further as part of the process evaluation (reported  
716 elsewhere) [42]. It was observed in the present study that daily sitting time appeared to be  
717 replaced predominately with stepping time, as opposed to standing time, in the  
718 intervention group at follow-up. This finding contrasts to that seen in adult samples within  
719 RCTs implementing sit-stand desks in the workplace, where sitting time is predominately  
720 replaced with standing time [65, 66]. A possible explanation for this finding could be that  
721 children may be less likely to stand still when using a sit-stand desk, and hence some

722 stepping movement could be recorded by the activPAL. Furthermore, rotating children  
723 around the class to facilitate their exposure to the sit-stand desks may also increase  
724 overall movement levels.

725

### 726 ***Study limitations and strengths***

727 Delays experienced at the start of the study meant that the duration of the intervention was  
728 shorter than originally proposed (2 school terms as opposed to 3 terms). Nevertheless, the  
729 overall duration was deemed appropriate to provide evidence of the feasibility and  
730 acceptability of the study protocol to inform the planning of a full trial. A further limitation  
731 was the relatively poor compliance to the activPAL protocol. Despite schools being  
732 stratified by their pupils ethnicity (either >50% South Asian pupils, or >50% White British  
733 pupils) with two schools from each stratum being randomised into the intervention and  
734 control arms, the balance between South Asian and White British participants across the  
735 two arms was not equal. This discrepancy was likely due to the ethnic composition of  
736 children in the individual classes involved in the trial, and discrepancies in consent from  
737 the individuals rather than an overall imbalance across the schools.

738

739 A key strength of this study includes the multi-method approach which enabled a thorough  
740 evaluation of all trial procedures. Other strengths are that the intervention was based on a  
741 theoretical framework, and its development was informed by the literature [23-25], our  
742 early work [33, 38], and public involvement (including focus groups with children and  
743 interviews with teachers and head teachers during the planning stages, along with ongoing  
744 consultation with teachers throughout the trial). The study setting, in terms of its location,  
745 associated demographics and school context, was a further strength of the trial. As noted  
746 earlier, Bradford was purposely chosen as the study location given its ethnic composition  
747 (predominantly South Asian and White British) and high levels of deprivation, health

748 inequalities and childhood morbidity [36]. The characteristics of the participating schools  
749 suggest they were largely representative of schools within the Bradford metropolitan  
750 district which enabled us to pilot this intervention under challenging circumstances. The  
751 acceptability and feasibility findings of this study therefore suggest that this trial would  
752 likely be feasible within other schools. The accessibility of the classroom-based setting to  
753 all children is furthermore important for addressing health inequalities. Forty-eight percent  
754 of the present sample were of South Asian ethnic origin. With the emergence of an  
755 increased cardiometabolic health risk profile observed in British South Asian children, in  
756 comparison to white British children [15], early health promotion interventions like this in  
757 such higher-risk groups, could be an important strategy for reducing ethnicity-related  
758 health inequalities later in life.

759

## 760 ***Conclusions and recommendations***

761 The present study demonstrated that recruitment and retention rates were adequate, and  
762 randomisation, the measurement procedures and intervention were generally acceptable  
763 to participants. Some modifications to the protocol are needed to ensure the successful  
764 conduct of a future RCT, particularly around improvements to the activPAL wear protocol.  
765 Preliminary evidence from this study has demonstrated the potential of the intervention to  
766 reduce children's weekday sitting time but more work is needed with teachers to create an  
767 acceptable classroom rotation plan to ensure pupil exposure to the sit-stand desks is  
768 maximised. The findings from this pilot cluster RCT therefore support the conduct of a full  
769 trial designed to evaluate the effectiveness and cost-effectiveness of a sit-stand desk  
770 intervention within the primary school setting on children's sedentary behaviour, markers  
771 of health and behavioural outcomes. As suggested elsewhere [26, 31], a full trial should be  
772 conducted over a minimum of one academic year. Such a trial could provide novel and  
773 robust evidence of the longer-term health and education impacts of this intervention.

774

775 **List of abbreviations**

776 RCT - randomised controlled trial; CI – confidence interval; METs - metabolic equivalents;  
777 UK - United Kingdom; CONSORT - Consolidated Standards of Reporting Trials; USA –  
778 United States of America; COM-B - Capability, Opportunity, and Motivation to perform a  
779 Behaviour; CTU - Clinical Trials Unit; Hz – Hertz; PEDS-QL - Paediatric Quality of Life  
780 Inventory; EQ-5D-Y - EuroQol 5-dimension Youth; SD – Standard deviation; MVPA -  
781 moderate-to-vigorous physical activity; cm – centimetres; kg – kilograms; BMI – body  
782 mass index.

783

784 **Declarations**

785 ***Ethics approval and consent to participate***

786 Ethical approval for the research was obtained from Loughborough University's Ethical  
787 Advisory Committee (reference: R16-P027). Head teachers, or a nominated senior  
788 teacher, provided written informed consent for their school to participate in the study.  
789 Teachers provided written informed consent for their participation, parents/guardians  
790 provided written informed consent for their child to participate in the trial evaluation, and  
791 participating children provided verbal and written assent.

792

793 ***Consent for publication***

794 Not applicable

795

796 ***Availability of data and materials***

797 Data supporting the results reported in this paper are stored at Loughborough University  
798 and are available upon request by contacting the first author.

799

800 ***Competing interests***

801 The sit-stand desks used in this study were supplied via an in-kind donation from Ergotron  
802 Inc, USA. The company played no role in the study design, data collection or data  
803 analyses, or in the preparation of this paper. The company have no relevant  
804 interests/rights in terms of project outcomes and uses. JS notes that she has a potential  
805 conflict of interest as her husband owns a business to manufacture height-adjustable  
806 desks for schools. These desks were not used in this research, and she was not involved  
807 in the data analysis. The remaining authors declare no other competing interests.

808

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814 Healthy Families theme. The views expressed are those of the authors and not necessarily  
815 those of the NHS, the NIHR or the Department of Health and Social Care.

816

817 ***Authors' contributions***

818 SC, SaB, CE, RME, LC, KT, GR, MF and StB obtained funding for the research, JS and  
819 DD were named collaborators on the funding application and supported the study  
820 throughout. DB, NP and YLC were the trial Research Associates. NBJ was the trial  
821 statistician and JA and GR undertook the health economics component of the study. All  
822 authors contributed to the development of the intervention and study methods, and all  
823 contributed to the reviewing and editing of the manuscript. All authors accept full  
824 responsibility for and have read and approved the final version of the manuscript.

825

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836

837 **List of Figures**

838 Figure 1. A Logic model for the Stand Out in Class intervention, applicable for a definitive  
839 trial.

840 Figure 2. A CONSORT Diagram for the Stand Out in Class pilot cluster RCT

841

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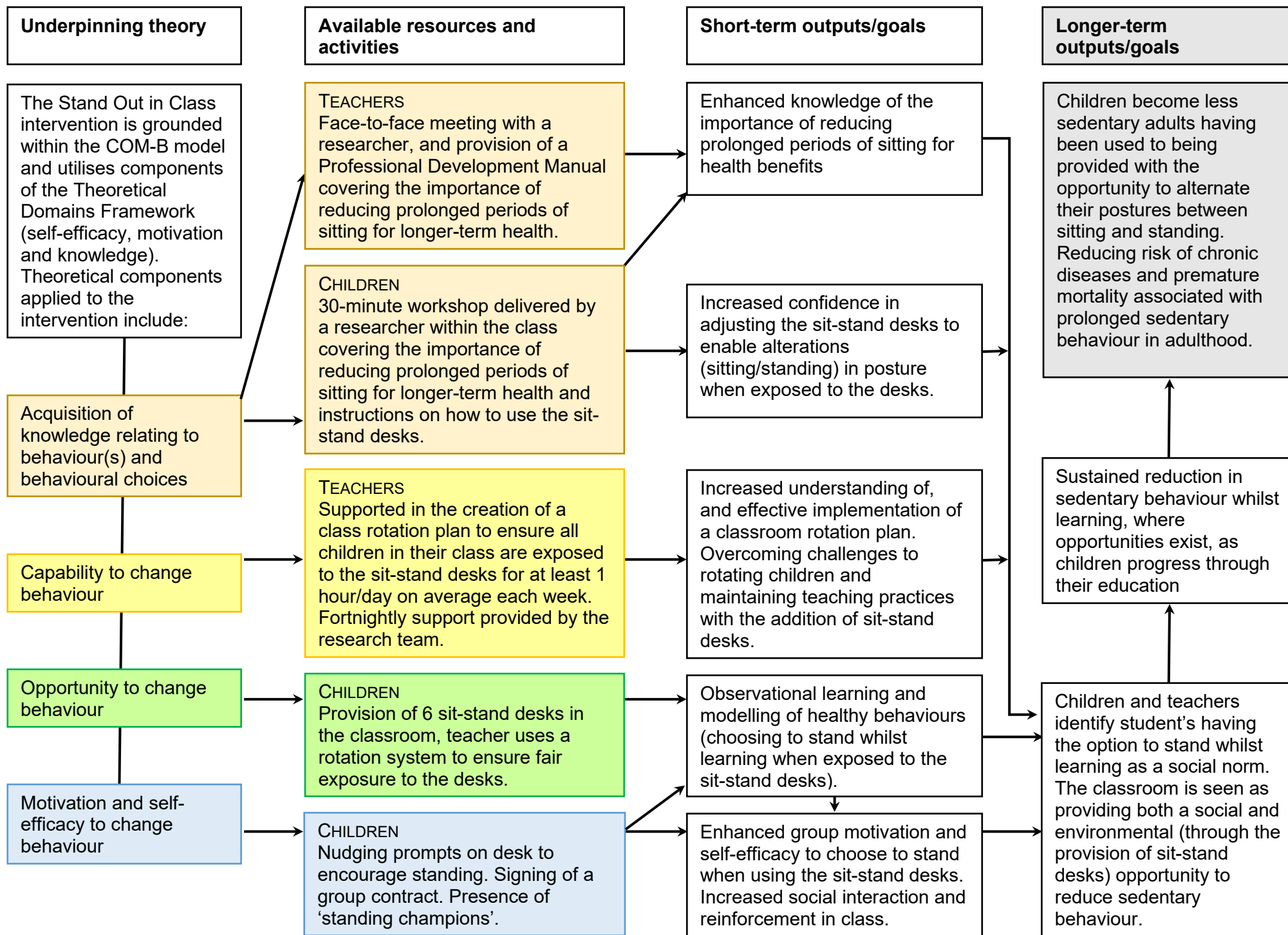
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# Enrolment

Schools assessed for eligibility (n = 24)

Schools Excluded (n = 16)  
 • Declined to participate (n = 12)  
 • No reply (n = 4)

Schools consented (n = 8)

Control (n = 4)

Schools randomized (n = 8)

Intervention (n = 4)

# Allocation

Pupils who consented at baseline (n=90/118)  
 • School 1 (n = 19)  
 • School 3 (n = 23)  
 • School 5 (n = 20)  
 • School 7 (n = 28)

Pupils did not consent at baseline (n=28/118)  
 • School 1 (n = 11)  
 • School 3 (n = 7)  
 • School 5 (n = 8)  
 • School 7 (n = 2)

Pupils who entered trial (n = 90/90)

Pupils who consented at baseline (n=86/116)  
 • School 2 (n = 20)  
 • School 4 (n = 23)  
 • School 6 (n = 18)  
 • School 8 (n = 25)

Pupils did not consent at baseline (n=30/116)  
 • School 2 (n = 10)  
 • School 4 (n = 7)  
 • School 6 (n = 11)  
 • School 8 (n = 2)

Pupils who entered trial (n = 85/86)

Pupils who did not attend at baseline (n=1)  
 • School 4 (n = 1)

# Follow-up (7 months)

Pupils who consented at follow-up (n=86/90)  
 • School 1 (n = 18)  
 • School 3 (n = 20)  
 • School 5 (n = 20)  
 • School 7 (n = 28)

Pupils lost to follow-up (n = 1)  
 • School 3 (n = 1)

Pupils who did not attend (n = 2)  
 • School 1 (n = 1)  
 • School 3 (n = 1)

Pupils who withdrew consent (n = 1)  
 • School 3 (n = 1)

Pupils who consented at follow-up (n=84/86)  
 • School 2 (n = 18)  
 • School 4 (n = 23)  
 • School 6 (n = 18)  
 • School 8 (n = 25)

Pupils lost to follow-up (n = 2)  
 • School 2 (n = 2)

# Analysis

Analysed (n = 90)

Excluded from analysis (n = 0)

Analysed (n = 86)

Excluded from analysis (n = 0)